K001528

JAN 1 8 2001

510(k) Summary
for
Modifications to PC Flow+ Spirometer

1. SPONSOR

Spirometrics Medical Equipment, Co.
22 Shaker Road
P.O. Box 680
Gray, ME 04039

Contact Person: Donald Clement
Telephone: 207-657-6700

Date Prepared: November 13, 2000

2. DEVICE NAME

Proprietary Name: PC Flow + (Model 3350)
Common/Usual Name: Diagnostic or Screening Spirometer
Classification Name: Diagnostic Spirometer

3. PREDICATE DEVICE

PC Flow + (Model 3350)
Flowmate III (formerly LTE)
Flowmate V Plus (formerly Flowmate II Plus)

4. DEVICE DESCRIPTION

The PC Flow + Spirometer which is the subject of this 510(k) is a modification of the original PC Flow + Model 3350. The modified PC Flow + includes the same sensor as used in the Spirometrics Flowmate III. In addition, slight changes have been made to the hand unit and the software has been rewritten to run on a PC with Windows instead of MS-DOS.

5. INTENDED USE

The PC Flow + is indicated for measuring the following pulmonary function parameters in a hospital, clinic, or industrial health screening locations for

patients at least five years of age: FVC; FEV 1 and 3; FEV1/FVC; FEF25-75; FEF 75-85; FEF 200-1200; FEF 50; PEF; FIVC; FIF 50; PIF; FEF 50/FIF 50; COPD index; Lung age; MVV; VC; Air trapping index; Methacholine Challenge.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The PC Flow+ is substantially equivalent to the original PC Flow+ that was cleared by 510(k) K900673 and to other spirometers marketed by Spirometrics. The technological characteristics and the indications for use of the PC-Flow+ have not changed. None of the modifications significantly affect the safety or effectiveness of the device.

The modified PC Flow+ was tested for compliance with the ATS standard for spirometers. In addition, testing was conducted for compliance with electrical safety standards and EMI/EMC standards. The PC Flow+ met the requirements of these standards. This testing demonstrates that the modifications to the PC Flow+ have not significantly affected the performance of the PC Flow+.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2001

Spirometrics Medical Equipment Co.
c/o Mr. James R. Veale
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K001528
PC Flow + Spirometer
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: November 13, 2000
Received: November 14, 2000

Dear Mr. Veale:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001528

Device Name: Spirometrics PC Flow +

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001528

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)